	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 06/2004)	DATE: Study ID: NAME:

APPROVAL PERIOD Oct 2, 2006 – Jun 19, 2007 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** Detroit Children's Health Study (M)

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1. WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to learn about respiratory health in children. Your child is being asked to be in the study because your child in 9-12 years old and resides in the Detroit metropolitan area and you completed a questionnaire about your child's health and were interested in your child participating in the clinical research study.

There will be about 200 children in this research study at Henry Ford Health System (HFHS).

This study is sponsored by the U.S. Environmental Protection Agency (EPA). This means that the EPA is paying HFHS for the costs of carrying out this research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

2. WHAT WILL HAPPEN IF MY CHILD TAKES PART IN THIS RESEARCH STUDY?

- **Presentation**: You and your child will watch a video presentation (6 minutes) describing asthma, asthma attacks and typical asthma triggers. The presentation will also show various examination stations that the child will go through as part of the clinic visit.

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- **Questionnaire**: The questionnaire will collect information about your child's recent health, including medications, diet, smoking, and recent physical activity. We will also ask you to list all of your child's medications.
- **Body size**: Your child will be asked to stand for height and weight measurements.
- **Vital Signs**: A HFHS staff member will measure your child's blood pressure and blood oxygen level.
- **Blood collection**: A trained HFHS staff member will collect 50ml (about 10 teaspoons) of blood from your child. The blood collection might be uncomfortable and leave a bruise. There is also a small risk of infection. Some participants may feel faint after the blood draw. A HFHS physician or nurse will be available during all clinical procedures. No more than two attempts to draw blood will be made. The EPA will be conducting genetic testing on the blood samples to see whether certain genes may be important in asthmatic responses.
- **Urine Collection**: Your child's urine will be collected in a container fitted to the top of the toilet lid.
- **Breathing capacity:** After a careful explanation of the procedure by a HFHS staff member, your child will be asked to take the deepest possible breath and then immediately exhale as quickly as possible until she/he can exhale no more air. The breathing vital capacity will be repeated 3 to 8 times. A new clean mouthpiece will be used for each participant.
- **Exhaled Nitric Oxide** After a careful explanation of the procedure by a HFHS staff member, your child will be asked to exhale a volume breath to measure nitric oxide, a gas we all exhale but when elevated may be an measure of lung swelling or inflammation. The filter/mouthpiece will be new for each child.
- **Fingernail/toenail clippings**: Your child will be asked to clip his/her fingernails and or toenails to be placed in two separate plastic ziplock bags. You can help them to clip their nails.
- **Smell test**: Your child will be ask to perform an odor identification test involving scratching and sniffing little paper bubbles containing various smells. Your child will try to identify 10 smells by marking one of four choices for each smell.
- **Home Air Sample Monitoring:** You may have been asked to participate in indoor and outdoor home air monitoring. You might have also been asked to bring in a used vacuum cleaner bag. You may keep the duffle bag that the EPA provided to you to carry in the samples.

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The clinical examination will take about 2 hrs to complete. There will not be a follow-up clinic visit. Your child's specimens will be analyzed within 3 years. There should not be any remaining biological samples left over after the study. If there are, the samples will be destroyed after 5 years.

3. WHAT ARE THE RISKS OF THE STUDY?

The breathing tests are no more stressful than blowing out the candles on a birthday cake. Repeated blowing in either or both tests may make your child feel dizzy. If so, the test will be stopped and your child will be allowed to rest before continuing. The blood draw will be performed by a skilled HFHS staff member who has experience drawing blood from children. The blood draw will be similar to any other blood draw that the child will have had during a typical physical or checkup. There is a small risk that your child may feel faint. A physician or nurse will be available at all times.

You should tell the person obtaining your consent about any other medical research studies your child is involved in right now. It is not expected that your child will have any complications or discomforts from being in this study. There may be risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

Research is designed to benefit society by gaining new knowledge. You will receive blood lead level information if your child's level exceeds the recommended safe level. Your child will receive a small gift if the child attempts to have his/her blood drawn. The EPA will mail some of test results to you and you can share them with your child's doctor. These will be the only benefits to you and your child other than compensation for samples provided during the clinic visit. The additional studies will not provide direct benefit to you or your child other than the satisfaction of participating in this research for the possible benefit of future generations.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to have your child participate in this study. You can choose to not participate in the study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your child's personal and health information for the purpose of this research study.

We may collect and use:

- New health information created during this study.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research.
- The U.S. EPA and their contractor staff at WESTAT.
- Other researchers at other institutions participating in the research.

Once your child's information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about your child from this study will not be placed into his/her medical record.

The EPA and HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your child's personal and health information will expire at the end of this research study.

If you decide not to sign this consent or cancel your consent, your child cannot participate in this study. If you notify us that you or your child wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

7. WHAT IF I AM INJURED?

It is very unlikely that your child will be injured as a result of taking part in this project. There is no federal, state, or other program that will compensate you or your child or pay for your child's medical care if your child is injured as a result of participating in this study. If you believe your child has suffered a research-related injury, you have the right to pursue legal remedy if you believe that your child's injury justifies such action. The Federal Tort Claims Act, 28 U.S.C. 2671, et seq., provides for money damages against the United States when property loss or personal injury results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. You and/or your child's medical insurance may have to pay for your child's medical care if your child is injured as a result of participating in this study. You are not giving up any of your or your child's legal rights by signing this consent form. Henry Ford Health System, the University of North Carolina and the EPA have not set aside funds to compensate you for any such complications or injuries, or for related medical care.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Ganesa R. Wegienka, Epidemiologist, or her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Dr. Wegienka at (313) 874-7393.

If you have questions about your child's rights as a research subject you may contact, anonymously if you wish, the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect the rights of research participants. You may also call the University of North Carolina's Institutional Review Board at (919) 966-3113 or email them at IRB_subjects@unc.edu; or you may call the Director of EPA's NHEERL Human Research Protocol Office at (919) 966-6217.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your child's participation in this research study is voluntary. If you or your child decides to participate, your child can stop at any time. If this happens, your child may be asked to return for a visit for safety reasons. Your family will get the same medical care from HFHS whether or not your child participates in this study. There will be no penalties or loss of benefits to which you or your child would otherwise be entitled if you or your child chooses not to participate or if you or your child chooses to stop your child's

participation once your child has started. You will be told about any significant information that is discovered that could reasonably affect your child's willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your child's participation in the research study at any time. If this happens, your child may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if your child participates in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

Compensation for Clinical Samples

Clinic Samples

Sample	**Monetary Compensation**	**Notes**
Blood, urine, fingernail (or toenail) clippings, odor identification test.	$65.00	See comment below
Lung function measurements (2)	$75.00	
	Total $140.00	

Following the blood draw, your child will receive a small gift. If two attempts are made to obtain the blood and your child then provides urine, nail clippings and perform the odor identification test, you will receive $65. If after giving assent for the blood draw, y our child refuses to attempt to have the blood sample taken, we will not ask your child to provide urine, fingernails (or toenail) clippings, or to do the odor identification

test, and no monetary compensation will be given for these tests. Whether or not they provide blood, your child will be asked to continue with the lung function measurements for which you could then receive $75.

Parents of children providing all clinic samples will receive a total of $140. However, only $75 will be provided to you at the end of the clinic visit. A check for the additional money will be mailed to you.

Compensation for Home Samples

Sample	**Monetary Compensation**	**Notes**
Vacuum dust bag	$25.00	
Asthma/allergy medications	$10.00	
Indoor/Outdoor passive badges	$50.00	See comment below
	Total $85.00	

Parents and children providing a list of asthma/allergy medications, home dust and air monitoring samples will receive up to an additional $85.00.

Comment: A select group of families were asked if they would be willing to have an air sample machine in their homes. If you volunteered to do these additional tests and are returning them today, you would qualify for compensation noted above.

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13. CONSENT

You have read this consent form or it has been read to you. You understand what your child is being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ _____ _____
Signature of Subject's Parent or Legal Guardian Date Time

_____
Print Name of Parent or Legal Guardian and Relationship to Subject

_____ _____ _____
Witness to Signature Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____ _____
Signature of Principal Investigator Date